UNITED STATE DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Case No.: 1:18- cv- 4814-AJN

JODI ROUVIERE, Individually and
ANDRE ROUVIERE, her husband, Individually,

Plaintiff

v.

DEPUY ORTHOPAEDICS, INC.,
DEPUY PRODUCTS, INC.,
DEPUY INTERNATIONAL, LIMITED,
JOHNSON & JOHNSON, INC.,
and JOHNSON & JOHNSON SERVICES, INC.,
and STRYKER CORPORATION,
STRYKER SALES CORPORATION, and
HOWMEDICA OSTEONICS CORPORATION,
d/b/a STRYKER ORTHOPAEDICS

Defendants

PLAINTIFF'S FIRST
SET OF INTERROGATORIES TO DEFENDANT, DEPUY ORTHOPEADICS, INC.

Plaintiffs Jodi Rouviere and Andre Rouviere., Inc., requests that Defendant DePuy Orthopaedics, Inc now known as Medical Device Business Services ("DePuy"), answer each of the following interrogatories fully, in writing and under oath, within the time required by Federal Rule of Civil Procedure 33. As required by Federal Rule of Civil Procedure 26, these interrogatories shall be deemed continuing so as to require prompt supplemental answers if Defendants obtain or remember further information.

DEFINITIONS

I. "Incident" refers to the events alleged in the Plaintiffs' Amended Complaint.

2. "Device" refers to the DePuy Summit Tapered Hip System's Summit stem component implanted in Jodi Rouviere on August 17, 2012 referred to in paragraph 6 of the Amended Complaint.

3. "Defendant," "you", or "your" means DePuy Orthopaedics, Inc

4. "Document(s)" has the same meaning as provided in the Federal Rules of Civil Procedure and includes without limitation all writings, notes, letters, reports, memoranda, drawings, graphs, charts, correspondence, photographs, x-rays, tapes, sound recordings, images, e-mails, texts, electronically stored information, and any other data or data compilations stored in any medium from which information can be obtained and translated, if necessary, by the respondent into reasonably usable form, in the actual or constructive possession, custody, care or control of Defendant or it's attorneys, including the originals and any non-identical copies, regardless of origin or location.

6. "Identify" when used with respect to a document means to state the type of document (e.g., letter) author, addressee, date and its present location and custodian. When used with respect to a person it means to state his or her name, last known address, and last known place of employment.

7. The term "concerning" means relating to, referring to describing, evidencing or constituting.

8. The use of the singular form of any word includes the plural and vice versa.

9. The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that otherwise might be construed to be outside of its scope.

INTERROGATORIES

1. Identify the manufacturer of any component part, subpart(s) or system(s) utilized in the manufacture of said product, the entity which manufactured the product and state the name and address of each entity within the distributive chain with regard to the product at issue herein, from the time of manufacture up to and including the time said product was implanted into the Plaintiff. If the Defendant manufactured the product, state: (a) the date and place of manufacture; (b) the date you sold or otherwise distributed the product; and (c) the name and address of the person or entity that purchased the product from you and indicate if the Defendant sells or otherwise distributes the product? If so, state: (a) the date on which the Defendant sold or otherwise distributed the product; (b) the names and addresses of all persons and entities that sold or otherwise distributed the product; and (c) the dates of sale and distribution for each such person or entity.

2. Identify all management, supervisory, engineering, technical, clerical and secretarial personnel for quality, reliability, product assurance, safety, field engineering, failure analysis, customer service, customer claims, components, standards, metrology, risk management, maintainability, materials, engineering, chemistry, and other organizations which would be involved in the reporting, analysis, investigation, data processing, settlement, corrective action, and tabulation of potential and reported incidents involving Defendant's product: at the time of manufacture or assemblies used in the subject model product; at the time that the subject model product was shipped from the manufacturer; and if you allege that any other person or entity or product manufactured by any other person or entity is responsible for the incident, provide the name title and address of that person or entity and fully provide the factual basis for the allegation.

3. Do you contend that the design, manufacture or distribution of the product was governed by any governmental and/or industry codes, standards, regulations or advisories? If so: (a) state the name and address of the governmental agency or department, or the industry office; and (b) specifically identify the codes, standards, regulations or advisories by title and numerical, alphabetical or other coded designation.

4. With regards to the Summit Tapered Stem, please state: the names, addresses and employment of the persons or firms that designed the device; what specialty field they represent (ie: bio chemist, engineer, immunologist, orthopedics etc.) the inclusive dates of such design and development; In answering this question, identify what department or other corporate division of Defendant had the responsibility for approving the design of the device before it was marketed for sale and also state the full name, job title, and present business and residence addresses of the person managing said department.

5. With regards to the Summit Tapered Stem, please state: When this model was first and finally assembled; where this model was first and finally assembled; where the component parts of this model were manufactured; where the component parts of this model were assembled; when the design used in this model was first used; the year in which models used titanium with porocoat and/or hydroxyapatite and/or duofix HA coating or any other surface alteration or coating, when were they first marketed by this Defendant; the quantity of the products using titanium, with hydroxyapatite coating and/or porocoat and/or duofix HA, or any other surface alteration or coating. in each year that the product was manufactured; the total number of products manufactured by Defendant in each of the years, the total sold and the gross revenue annually from those sales; the name, address, and job title of the person or persons who drew up the specifications for the product and/or any of its component parts. For each, state: the date said specifications were completed; the name and address of each person or entity who or which has possession, custody or control of any such document.

6. Identify any and all clinical trials on any and all hip systems that include the Summit Tapered Stem and all explant retrieval programs on any and all hip systems that include the Summit Tapered Stem, any and all results of their analyses performed since the inception of the product. Include for each and every unit tested; who tested it, name address and phone number of the person or organization who tested it, on what date it was tested, what the findings of each test were, when the Defendant became aware of those testing results and what the Defendant's role in the study was specifically.

7. State whether the Defendant intends to assert any defenses at the time of trial. (a) If so, and the defenses are based upon the common-law, state the principle involved and fully provide the factual basis for any such defense. (b) If so, and the defenses are based upon a statute, regulation or other written rule, identify each such statute, regulation or rule and fully provide the factual basis for any such defense. (c) If so, and your defense is based upon an alteration, use, misuse of or other change in the product, indicate each such defense and fully provide the factual basis for any such defense.

8. How many products, of the type or model in question, were manufactured and sold by Defendant, giving the date when the manufacture of each was started and the date when the manufacture of same stopped, if stopped. And dates sold and total number of units sold to date, both singularly and in conjunction with a particular hip system, including the total proceeds received from said sales by the Defendant. Please identify each and every component part of the product's sub-assembly or assembly which Defendant did manufacture or licensed to be used under any other product name that used the Summit Tapered Stem in their system, including but not limited to other stems that included Hydroxyapatite, Porocoat and/or Duofix HA coatings.

9. Please identify any and all information within the knowledge of the Defendant regarding knowledge of the use of the Summit Tapered Stem within any other hip system, DePuy or any other manufacturer, or components by the Summit name or by any other name. Identify which manufacturer and which specific hip system it was combined with, what name it has been marketed under, and the date the Defendant was made aware of such. If this was a product(s) was ultimately cleared through the 510K process, please list the 510 K number(s), and any related device approvals, denials and clearances including date and description of notice.

10. Regarding the Summit Tapered Stem, please identify each and every memorandum, email, letter, or any form of external or internal document of any kind prepared by any employees or consultants to DePuy raising any concerns regarding the safety or adverse events concerns, design issues or flaws or possible harm the device could cause a recipient from its initial design when it was first created and up to the present time. Please identify the date the memorandum or document was authored, the author of the document or memorandum, the recipients of memorandum or document, what the main topic of the memorandum or document was and where each memorandum or document can be located currently.

11. State the name, address and job title of the person who has custody of all records pertaining to the Summit Tapered Stem, relating to the formulation and composition of the wording of any affixed, attached, or otherwise supplied labels, tags, directions, instructions, warnings or other writings, whether attached thereto or not, which accompanied the product and identify the labels, tags, directions, instructions, or other writings, please state: the purpose of any of these affixed labels, tags, directions, instructions or other writings; the complete and verbatim contents of these labels, tags, directions, instructions, or other writings; the position or location of any labels, tags, directions, instructions or other writings on the product; and identify any label, tag, direction, instruction or other writing not on or attached to the product which accompanied the product at the time it left your control for marketing purposes. If Defendant did not distribute any printed warnings regarding the subject device or warning of the potential for injury resulting from the use of the product prior to the implantation of the device, does Defendant do so at the present time and if so please state: the date each such printed matter was published or distributed; the wording of the warning statements; the detailed description of the document which contained such warning; and the name, title, and address of the person who has custody of the records concerning these brochures, pamphlets or other printed materials.

12. Were there any writings or warnings on the product itself, on its packaging, or on anything attached or appended to the product, when it left the Defendant's control? If so, state specifically and fully the exact words used and their location. If a warning was given in other than words, describe any and all symbols or depictions used. State whether the Defendant provided to a distributor, possible user or any person or firm that the Defendant expected to come in contact with the product, any form of written material, such as a surgical technique guide, design rationale patient guide or any other writing pertaining to the product. State with specifically what was written or depicted. If, from the date the product was manufactured until the date of the incident, any writings or warnings pertaining to the product were added, altered, or otherwise changed, state: (a) the date of each such change; (b) the specific words or symbols used in each such change; (c) the name and address of the officer, managing agent or other person(s) in your organization most involved with such change; and (d) the names and addresses of all of your employees who were involved in such change.

13. State whether Defendant or any agent, employee, independent contractor or other representative of Defendant has conducted any recall campaigns, technical service bulletins, operations, warnings, programs, or activities which involved the product. If the answer is in the affirmative, please state: the exact date of the announcement or beginning of said campaign or operation; the purpose of said campaign or operation in terms of potential or real defects sought to be checked and/or corrected; the type or model of the product involved in the campaign or operation; the number of products of each type examined or corrected; whether the product defect was examined or corrected; the date and location of the examinations or corrections; the address of the person performing the examination or correction; describe any such recall in complete detail; and the name, title and address of each person or entity having custody of any or all records relating to each such recall campaign.

14. Please describe in complete detail the substance and contents of all claims or representations made regarding the Summit Tapered Stem or any hip system it was a part of from its inception to the date of the answers to these interrogatories by Defendant as to the quality, safety or fitness of the product in question, or similar products including component parts and coatings.

15. State in detail all design modifications or alterations that have been considered for the product and component parts from the date of design to the present. As to each such modification or alteration, please state: whether or not it was adopted, and if not, the reasons for rejection; the individual or individuals (by name, title and business address) who proposed such change; and the problem or potential problem intended to be addressed, ameliorated or corrected by the design, modification or alteration.

16. Fully identify, giving the full citation of, and describe, stating the substance of, each rule, regulation or standard promulgated by any governmental agency, standards institute, safety institute or organization, or any other industry group or organization, which is applicable to the product described herein and which Defendant claims it complied with in the manufacture of the product in question; and fully identify, giving the full citation of, and describe, stating the substance of, each rule, regulation or standard promulgated by any governmental agency, standards institute, safety institute or organization, or any other organization, which is applicable to the product described herein and which Defendant admits it did not comply with in the manufacture of the product in question and identify fully each test or standard with which Defendant complied in the design, production or safety specifications of the product and similar products, including component parts. In doing so, identify each independent laboratory and/or consumer protection group and/or governmental agency which conducted tests on the device and if there were any safety concerns for the product at issue by any independent laboratory and/or consumer protection group and/or governmental agency that conducted tests on the product in question or other related products please state the date of the recommendation; The name and address of the independent laboratory, consumer protection group, and/or government agency; The type of test that the independent laboratory (or consumer protection group or government agency) conducted; The substance of any oral recommendations that were made; and The name, address, and job title of the person who has present custody of written recommendations of any independent laboratory, consumer group, and/or government agency.

17. State whether or not Defendant or any agent, employee, independent contractor or other representative of Defendant is a member of any product, procedure, reliability, quality, safety, testing or standards committees, and/or of any industrial or professional society and please state for each such person or entity: the full, name, address, job title, or capacity of each member; the organizations, committees, and sections to which each belongs; and the title, publisher and date of publication of each article or technical paper authored, co-authored, co-authored or sponsored, in whole or in part, by such person or entity.

18. At any time to date, did Defendant have any written policies, procedures, or instructions directed to its employees or its field systems regarding defect reporting because of safety related and non-safety related failures or defects when the products were in consumers' possession or the possession of hospital or physicians possession or other distributor and if so, describe the extent, if any, in which (a) hospitals doctors office, suppliers and distributors to Defendant participated in the reporting systems did; (b) Defendants' distributors, dealers and service facilities participated in the reporting systems referenced in the preceding interrogatory; (c) independent distributors, dealers and service facilities participated in the reporting systems referenced in the preceding interrogatory. Does Defendant have any communications, both internal to the organization and between Defendant and its customers, vendors, suppliers, servicemen, technicians, dealers, distributors or governmental agencies, relative to problems, hazards, failures, adverse event report or defects related to the device or any of its parts, components, sub-assemblies or assemblies and Does Defendant have any reports, both statistical and management, on any defects, rejections and/or failures of parts, components, sub-assemblies or assemblies used in the subject model product?

19. Does Defendant have any reports, memoranda or resulting test data relating to any defects, failures, or corrective action proposed or associated with any of the parts, components, sub-assemblies or assemblies which would reflect the "failure rate" of the device? If so, please identify the name of the report, memorandum or test data, the date it was created, who authored it, what the basis of the report, memoranda or resulting test data was and where a copy of it can be located.

20. State whether or not Defendant has ever been cited, criticized, reprimanded, had any correspondence with, public hearings on or had legal action taken against it by any public official, governmental agency, or body because of alleged violations of any federal, state or local statute or regulation with regard to the manufacture, design, distribution, safety, advertising, or sale of the product. With regard to each such activity state: the exact date of the announcement or beginning of the activity; the name and address of the person or entity who or which commenced the activity; the purpose of said operation in terms of potential or real defects sought to be checked and/or corrected; the type or models of the product in the operation; whether the problem was examined or corrected; the date and location of the examinations or corrections; the address of the person performing the examinations or corrections and the name and address of each person or entity having possession, custody or control of records relating to such activity.

21. State whether at any time prior to answering these interrogatories and subsequent to the date of manufacturing or distribution of the product itself or other products which include the device by this Defendant, any person complained or alleged, either verbally or in writing including but not limited to reports to and from governmental agencies, trade publications articles, customer complaints and adverse event reports, correspondence to or from the Consumer Product Safety Commission or its predecessor agencies, etc., that he, she or anyone suffered any adverse events (including bodily injury or death) as a result of using the product. If so: (a) identify all such claimants and their attorneys; (b) describe as specifically as possible the product involved, including but not limited to the model and serial numbers; and (c) if a lawsuit was instituted against the Defendant, state the names and addresses of the claimants, their attorney(s) and the court in which such claim was instituted. Please also list the date, person or company name and contact information for said correspondence and a description of each correspondence.

21. Describe in detail each and every safety test and reliability test conducted on the Summit Tapered Stem including but not limited to; porous structure characterization- physical, chemical or mechanical, Femoral Head Fatigue Testing, Femoral Neck Fatigue Testing, Axial Disassemble Testing, Fretting and Corrosion Testing, Cup and Liner Disassembly Testing, Screw Characteristics Testing, Ceramic Femoral Head Comparative Burst Testing, Ceramic Femoral Head Fatigue and Post-Fatigue Burst Testing, Ceramic Femoral Head Axial Disassembly Testing, Ceramic Femoral Head Torque Testing, Pyrogenicity Testing, Hip Stem Testing, Determination of Static and Cyclic Fatigue, Strength of Ceramic Modular Femoral Heads, Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip, Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip, Determination of endurance properties and performance of stemmed femoral components, Endurance properties testing and performance requirements of neck region of stemmed femoral components, Arthroplasty Femoral Components Without Torsion, Arthroplasty Femoral Components with Torsion, Diametrical clearances and tolerances, Preclinical Laboratory testing, Adverse events and A Kaplan-Meier Survivorship Analysis, Biochemical testing, Medical Device Biology and Biological Assessment, Identifying pathological biomarkers testing, Chemical and surface analyses, Forging Trial Results, Raw material specifications: chemical composition product analysis tolerances, physical properties, mechanical properties, dimensional tolerances, or any testing required by or submitted to any appropriate competent regulatory authority (e.g. Food and Drug Administration (FDA)) and any revision documents to original applications or reports. Please list testing certifications on the subject device and state specifically the type of test, the name and contact information for each person or company involved in performing the test, the date of the test, the reason for such test and all of the results of each and every such

test. This response should be inclusive of any and all testing done by both the manufacturer and outside facilities or regulatory agencies.

23. State whether Defendant claims that the existence of any hazardous, dangerous, defective or unsafe condition of the subject model product was not foreseeable to Defendant and/or its servants, agents or other representatives prior to the occurrence made the basis of this suit. If so with specificity, please state its basis as to why the hazardous, dangerous, defective or unsafe condition of the subject model product was not foreseeable.

24. Please indicate any and all other names or identities the Defendant is operating under or has operated under or any affiliation with any trade organization, websites or industry group that promulgates written standards, habits or customs, instruction manuals, videos, photos, articles, product manuals or rationale, product compatibility charts, patient testimonials, result of safety testing, clinical trials or any other material pertaining to the product. Identify each online networking site, social networking site and/or internet blog on which the Defendant or anyone acting on the behalf of the Defendant has participated and/or logged into during the time from August 17, 2007 to the present including but not limited to professional and consumer orthopedic-related sites, Facebook, Twitter, MySpace, Instagram, Pinterest, Vine, Tumblr, Google+, SnapChat, LinkedIn and YouTube, and for each such site provide the name by which the Defendant or anyone acting on the Defendant's behalf identify or identified themselves (including display and/or user names) and with which Defendant anyone acting on the Defendant's behalf registered for the account and state how long Defendant anyone acting on the Defendant's behalf has been a participant or member of the blog.

25. What materials do you contend to were supplied or should have been supplied at the time the Plaintiff submitted to the implanting or following the implanting of the device in AUGUST 2012 by the manufacturer, distributor or sales person, or by the Defendant in general, either written or verbal, that constituted a warning to the Plaintiff that the Defendant contends was an adequate warning; and in doing so indicate each and every source of said warning either from, packaged material, labeling, advertisements, pamphlets, oral presentation or by any manner whatsoever. Please indicate what materials were given to which entity (surgeon, patient, distributer, etc.) and in what manner they were presented or represented.

CERTIFICATION

I hereby certify that the foregoing answers to interrogatories are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment. I hereby certify that the copies of the reports annexed hereto provided by either treating physicians or proposed expert witnesses are exact copies of the entire report or reports provided by them; that the existence of other reports of said doctors or experts are unknown to me, and if such become later known or available, I shall serve them promptly on the propounding party.

Sign: _____

Print: _____

STATE OF _____)
)
COUNTY OF _____)

BEFORE ME, the undersigned authority, personally appeared _____, who after first being duly sworn, deposes and states that the foregoing Answers to Interrogatories are true and correct.

SWORN TO AND SUBSCRIBED before me this _____ day of , 2019.

_____
NOTARY PUBLIC, State of _____

Notary Printed Name:_____
My Commission Expires:_____
Personally Known _____ Produced Identification _____
Type of Identification Produced:_____
Oath Administered _____ Oath not Administered _____

WE HEREBY certify that a true and correct copy was electronically forwarded to: Joe Eaton, Barnes & Thornberg, LLP 11 South Meridian Street, Indianapolis, Indiana 46204; Joe.Eaton@Btlaw.com James Francis Murdica, Barnes & Thornburg LLP, 43 West 43rd Street, Suite 175, New York, NY, US 10036, jfmurdica@pbwt.com this ***21st day of February 2018***.

JODI ROUVIERE, PRO SE Plaintiff
4070 Laguna Street,
Coral Gables, Florida 33146
Tel: (305) 608 8076

By:_____

ANDRE ROUVIERE, PRO SE Plaintiff
4070 Laguna Street,
Coral Gables, Florida 33146
Tel: (305) 790 9325

By: _____